

REMARKS

This Paper is respectfully submitted in response to the Office Action rendered in the above-identified patent application on April 19, 2006. It is timely in view of the Petition for Extension of Time filed concurrently herewith.

Claims 1-22 and 68-71 are pending. Claim 2 has been amended with this Paper to correct the use of the term "extract" and replace it with the correct term, —compound— having basis in claim 1. Claim 71 has been added. It finds basis in original claims 1 and 6 and in the Specification at p. 16, l. 12-20, *inter alia*.

The Office Action of April 19, 2006 rejected claim 2 under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants respectfully request reconsideration of this rejection in view of the correction to claim 2 set forth in the amendment above.

The Office Action of April 19, 2006 again rejected claims 1-3, 6, 7, 9, 16, and 19 under 35 U.S.C. 102(e), as being anticipated by Costanzo (US 6,323,219). (Office Action p. 3) Applicants respectfully request reconsideration of this rejection in view of the ensuing discussion.

As set forth previously in Papers submitted on September 27, 2004 and February 8, 2005, applicants again respectfully submit that Costanzo neither suggests nor describes methods for using the composition of applicants' invention to affect hair growth. Applicants respectfully call attention to the fact that skin and hair pigmentation are not identical. For example, hair color might turn gray upon aging, but skin color does not show a similar effect. Moreover, it is well-known that hair growth is not related to hair color; both naturally-pigmented hair and gray (non-pigmented) hair can grow to different lengths and thicknesses. "Hair appearance" includes not only color, but also hair density, thickness and length, and the appearance of hair in undesired locations (e.g. female facial or leg hair, male beard area).

As set forth in the claims, Applicants make clear that according to applicants' methods, the composition is to be applied to **mammalian hair in need of a change in appearance**, emphasizing the reduction in visibility of unwanted hair growth by reducing hair follicle dimensions and reducing the growth rate of the hair shaft.

Costanzo, however, suggests the opposite, i.e., darkening gray hair. While Costanzo is a composition of melanin combined with a phagocytosis-enhancing agent, intended to induce coloration of gray hair, the compositions and methods of applicants' invention use trypsin **inhibitory** activity to reduce the visibility of undesired hair, to thin hair, to slow hair growth, and to enable management of "difficult hair" (e.g. Afro American hair, pseudofolliculitis barbae hair) by slowing hair growth parameters.

Applicants respectfully submit that Costanzo neither explicitly nor inherently describes or suggests the methods and compositions of applicants' invention. As set forth in the ensuing discussion, Costanzo's only reference to use of *any* composition on hair relates to a composition *different* from that set forth in applicants' claimed invention. Moreover, Costanzo's topical use on the skin of compositions containing soymilk, for example, would not have inevitably led to use of the methods of applicants' claimed invention.

The only statement set forth in Costanzo that relates to hair treatment is as follows:

Skin disorders include unwanted pigmentation, unwanted depigmentation, psoriasis, rashes, and certain physical skin imperfections (e.g., wrinkles). In one specific example, vitiligo patients are treated with melanin (via liposomes or plain) together with a phagocytosis-increasing agent (e.g., SLIGRL) to darken the light spots. Alternatively, they are treated with Compound I to lighten the darker sites (see U.S. Ser. No. 09/110,409, filed Jul. 6, 1998). *In an example related to skin disorders, gray hair is treated with melanin (plain or liposome-delivered) and phagocytosis-increasing agent (e.g., SLIGRL), ideally in a shampoo or cream.* Central nervous system disorders include, without limitation, Alzheimer's disease and other senile plaque disorders (treated via up-regulating the phagocytosis of amyloid fibrils), depression, phobic disorders, and other disorders resulting from secondary effects of benzodiazepine treatment. [Costanzo, col. 30, l. 14-32] (emphasis added)

Clearly, Costanzo distinguishes between treating darker skin sites with trypsin inhibitory products such as Compound I and darkening gray hair using SLIGRL, a PAR-2 **agonist and phagocytosis-increasing agent**.

Thus, the only suggestion in Costanzo for use of compositions on hair requires treatment of gray hair with melanin and a phagocytosis-increasing agent, SLIGRL. SLIGRL is not a member of the botanical families set forth in the compositions of applicants' invention. It is a *phagocytosis enhancer* applied in conjunction with melanin,

not a serine protease inhibitor. Thus, Costanzo does not suggest or describe the application of compositions of applicants' invention on hair. While the Office Action indicates that both SLIGRL **and** Compound I are included in the Costanzo composition [Office Action, p. 4], Costanzo does no such thing. They are, in fact, compounds that have exactly the opposite activity of each other. In fact, this is illustrated in Figure 2, which demonstrates SLIGRL's PAR-2 agonist activity and Compound I's inhibitory activity very clearly. Costanzo nowhere suggests or describes compositions containing **both** PAR-2 agonists and inhibitors. [See also Costanzo, col. 2, l. 42-50].

Furthermore, in response to the argument that the compositions of Costanzo would inherently and inevitably lead to the methods and compositions of applicants' invention, even if one were to follow Costanzo in applying compositions topically to skin, the result would not *inevitably* be that of the methods of applicants' invention, as required in order to serve as a basis for an inherency rejection. Following Costanzo's application of compositions to skin would not necessarily and inevitably lead to one of ordinary skill in the art applying such compositions to hair in need of changing in accordance with the methods of applicants' invention. For example, one would apply skin color reduction compositions to quite different parts of the body (e.g. age spots) from those for which hair management would be needed or desired (e.g. scalp, beard, legs).

Moreover, Costanzo's only reference to hair itself relates to darkening gray hair, but not to reducing hair color or visibility. It clearly does not mention any effect on hair growth parameters. Indeed, the only effect on gray hair set forth in Costanzo is providing *exogenous* melanin to "stain" gray hair. In contrast, the methods of applicants' invention perform the opposite, i.e., reducing hair visibility by reducing growth and *endogenous* melanin production, or reducing hair growth to manage making it grow slower, and appear thinner.

Applicants respectfully submit that Costanzo does not teach the methods of claims 1-3, 6, 7, 9, 16 or 19. These claims are directed to methods for effecting changes in mammalian hair appearance and hair pigmentation, and reducing hair growth, and hair follicle and hair shaft size by a topical application of a topically active composition containing one or more compounds derived from one or more botanical families

leguminosae, solanaceae, gramineae and cucurbitaceae. Costanzo does not meet these limitations and therefore does not anticipate the invention. Nor would it be inherent that the invention of Costanzo would affect the hair as required by the rejected claims.

Therefore, in view of the foregoing discussion, Applicants respectfully request reconsideration of the rejection under 35 U.S.C. 102(e) in view of Costanzo in view of the foregoing discussion.

The Office Action also rejected claims 4, 5, 8, 10-14, 16-18, 20-22 and 68-70 under 35 U.S.C. 103(a) as being unpatentable over Costanzo (US 6,323,219) in view of Matsuura et al (US 6139899) ("Matsuura") [Office Action, p. 6]

Applicants respectfully request reconsideration of the rejection under 35 U.S.C. 103(a) in view of the ensuing discussion.

As discussed above, and in previous papers, Costanzo neither suggests nor discloses the methods or composition of applicants' claimed invention, explicitly or inherently. For the same reasons set forth above in connection with applicants' discussion of Costanzo, one of ordinary skill in the art would not have been led to the methods or compositions of applicants' invention by Costanzo: (a) the only suggestion to use the compositions of Costanzo on hair require both melanin and SLIGRL, *not* the compositions of applicants' invention; and (b) topical use of compositions set forth in Costanzo would not have inherently resulted in the methods of applicants' invention.

Matsuura et al. relates to ingestible soymilk products that have been treated to contain high ratios of malonylisoflavone glycosides. Matsuura et al. clearly relates to ingestible soybean milk products as evidenced by the following description:

An object of the present invention is to provide soybean milk having a **satisfactory flavor** and soybean milk-related products prepared therefrom. Matsuura, et al., Col. 1, l. 34-36] (emphasis added)

Thus, the compositions of Matsuura et al. do not contain soy trypsin inhibitor, as required by the compositions and methods of applicants' invention. As is well-known to those of skill in the art, soy trypsin inhibitor (STI) causes severe diarrhea and gastrointestinal effects if one ingests it. Thus, soy products are heated to high temperatures in order to eliminate such enzymes, as stated in Matsuura, et al.:

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It is necessary to heat the resulting slurry at 70°C. or higher to inhibit the actions of various enzymes of soybeans and to deactivate the enzymes rapidly.
[Matsuura, et al., col. 2, l. 17-19]

Thus, whether or not Matsuura et al. contains isoflavones, its combination with Costanzo would not have led one of ordinary skill in the art to the compositions and methods of applicants' invention. Rather, it would have taught away from these compositions and methods, as Matsuura et al. describes soymilk compositions that do not contain STI. Not only do Matsuura et al.'s composition not contain STI, they are intended for internal ingestion and nowhere does Matsuura et al. suggest their use topically or on hair follicles.

Costanzo does not disclose or suggest the use of his composition to affect hair pigmentation as discussed above. Costanzo also does not disclose or suggest methods of effecting change in hair growth, reducing hair follicle and hair shaft size. Matsuura et al. does not compensate for the deficiencies of Costanzo in these or any other regard. Therefore, applicants respectfully request reconsideration of the rejection of claims 4, 5, 8-14, 16-18, 20-22 and 68-70 under 35 U.S.C. 103(a).

Therefore, in view of the foregoing discussion and amendments, Applicants respectfully request reconsideration of the rejections set forth in the Office Action of April 19, 2006. An early allowance is earnestly solicited.

Respectfully submitted,

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